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| 10/524,632 | 02/16/2005 | Hideo Nawata | TEI-0131 | 1448 |
| 7590 Rader fishman & Grauer 1233 20th Street N W Suite 501 Washington, DC 20036 | | | | |
| 01/21/2009 | | | | |
| EXAMINER | | | | |
| MATTER, KRISTIN CLARETTE | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,632

Applicant(s)

NAWATA, HIDEO

Examiner

KRISTEN C. MATTER

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date 6/9/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the amendment filed 11/4/2008. Claims 1, 2, and 4 have been amended, claim 5 has been added, and no claims have been cancelled. Currently, claims 1-5 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/9/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner, including WO 01/04528. Examiner apologizes for any inconvenience.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “adsorption-type” renders the claim indefinite because it is not clear what elements are included the “-type,” rendering the claim unascertainable. It is unclear if the oxygen generating means has to be an oxygen adsorption concentrating means or not, and if not, what components must be similar to an oxygen adsorption generating means? Examiner suggests deleting “-type.”

Claim Rejections - 35 USC § 102/35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gropper et al. (US 5,540,220). Gropper et al. discloses an oxygen supplying apparatus comprising a respiration sensor (40) which detects the respiration of the user and provides a respiration signal, a supply method setting means (98) which selects the supply in continuous flow or in synchronism with the user (see column 5, line 41 and column 17, lines 33-36 also, which implies that the system is capable of being set in a variety of continuous flow modes by manual selection of the user; the supply method setting means is then carried out by the assist module if turned on and available during a given time in the cycle), a flow rate setting means (78) for supply of a set value for flow rate that is entirely independent of the supply method setting means, and a controlling means (46) that controls the aperture of an automatic closing valve (68) corresponding to the supply flow rate set value by receiving a supply method setting signal of the continuous flow, or opens the automatic closing valve on the inhalation starting point based on the respiration signal by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of the automatic closing valve corresponding to the flow set rate value, wherein the closing valve is controlled by the controlling means which had taken the information set by the supply method (assist trigger signal) and the flow rate setting means (see column 8, lines 40-60 and column 17, lines 5-31).

Gropper et al. does not specifically disclose an oxygen generating means (examiner notes however that the oxygen generating means is part of the preamble only and does not appear to give much patentable weight to the claims). However, oxygen generating means are well known and commonly used for supplying oxygen to patients in breathing devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used oxygen generating means as the “conventional pressurized [oxygen] source” of Gropper et al. in order to supply oxygen to the patient without the need of pure oxygen cylinders, for example. Furthermore, it appears as though the device of Gropper et al. would perform equally well with an oxygen generating means/supply.

Claim Rejections - 35 USC § 103

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gropper et al. Gropper et al. is silent as to the response time and diameter of the closing valve. However, the flow rates to be delivered in the instant application and the prior art are similar and absent a critical teaching and/or a showing of unexpected results from having the closing valve have a response time of 0.1 seconds or less and a diameter of 1-5 mm, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the closing valve of Gropper et al. with a response time of less than 0.1 seconds and a diameter of 1-5 mm in order to allow the desired flow rates to be delivered to a patient efficiently and safely. Furthermore, a mere change in dimension does not patentably distinguish the invention over the prior art. Also, given that the closing valve of the instant application is commercially available (see page 10) and that the device of Gropper et al. has no structure that

would prohibit the use of the claimed closing valve, it appears as though the device of Gropper et al. would perform equally well with a closing valve having a response time of less than 0.1 seconds and a diameter of 1-5 mm.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gropper et al.

Gropper et al. does not specifically disclose an adsorption-type oxygen generating means. However, pressure variable adsorption-type oxygen concentrating means provided with adsorption cylinders packed with adsorbent that adsorbs nitrogen rather than oxygen are well known and commonly used for supplying oxygen to patients in breathing devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an adsorption-type oxygen generating means as the “conventional pressurized [oxygen] source” of Gropper et al. in order to supply oxygen to the patient without the need of pure oxygen cylinders, for example. Furthermore, it appears as though the device of Gropper et al. would perform equally well with an adsorption-type oxygen generating means/supply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/569,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claim 1 is a broader version of the copending claim 8 (i.e. the instant claim 1 does not include the structural element of the exhaust means or pressure measuring means as in the copending claim 8). In the instant claim 1, the structural elements are included in the copending claim 8. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-5 do not differ from the scope of the copending claims 1-17.

Response to Arguments

Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments involving the 112, 2nd paragraph, rejection of claim 4, examiner notes that even though "adsorption-type" concentrating means are disclosed in the specification, those limitations cannot be read into the claims. As discussed above, the term "-

type" makes it unclear as to how similar the generating means has to be to an adsorption concentrating means.

Also, examiner notes that supplemental arguments were filed on 12/2/2008, but those arguments do not appear to present any new arguments from those submitted on 11/4/2008 and are also moot with the newly added limitations to the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Press et al. and Melker et al. are cited to show other automatically controlled ventilators with mode and flow rate setting means.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771